SEP - 6 2000



K00 2158

# Premarket Notification 510(k) Summary
## As required by section 807.92
## S/5™ Compact Critical Care Monitor
## with S-00C03 or S-00C04 software

**GENERAL COMPANY INFORMATION as required by 807.92(a)(1)**

COMPANY NAME/ADDRESS/PHONE/FAX:

Datex-Ohmeda, Inc.
3 Highwood Drive
Tewksbury, MA 01876
Tel: 978-640-0460
Fax: 978-640-0469

NAME OF CONTACT:

Mr. Joel Kent
FDA Official Correspondent

DATE:

July 14, 2000

DEVICE NAME as required by 807.92(a)(2)

TRADE NAME:

S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software

COMMON NAME:

Patient monitor

CLASSIFICATION NAME:

The following Class III classifications appear applicable:
Monitor, Physiological, Patient with Arrhythmia detection or alarms (per 21 CFR 870.1025)
Arrhythmia detector and alarm (per 21 CFR 870.1025)
Monitor, ST segment with Alarm (per 21 CFR 870.1025)

NAME OF LEGALLY MARKETED DEVICE FOR WHICH A CLAIM OF SUBSTANTIAL EQUIVALENCE IS MADE as required by 807.92(a)(3)

The Datex-Ohmeda S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software is substantially equivalent when compared to CS/3™ Monitors (K974792), and for bedside arrhythmia analysis and drug calculator as compared to CS/3 Critical Care Monitor with S-ICU99(A) software (K000168).

DEVICE DESCRIPTION as required by 807.92(a)(4)

The S/5™ Compact Critical Care Monitor with S-00C03/4 software uses several types of plug-in measurement modules. Modules are the subject of separate 510(k)'s and are not part of this notification.

The S/5™ Compact Critical Care Monitor with S-00C03/4 software is typically furnished with a module that measures ECG, invasive and non-invasive blood pressures, pulse oximetry and temperature. Modules are placed in the S/5™ monitor frame and are automatically recognized by the monitor. The patient cables are connected to the module plug in jacks and then monitoring can begin.

The S/5™ Compact Critical Care Monitor with S-00C03/4 software can display measurements in the form of numeric values, traces and trends. Audible and visual alarms are used to indicate patient status. The priority profile of an alarm depends on the parameter.

The S/5™ Compact Critical Care Monitor with S-00C03/4 software is operated by a keyboard. Typically pressing a key results in a pop up menu appearing on the screen. Selections can then be made easily from the menu using a unique ergonomically designed pointing device on the keyboard called a ComWheel™. The S/5™ Compact Critical Care Monitor has a built in color LCD display and also a built in NiMH (Nickel Metal Hydride) battery option. The software S-00C03/4 performs some module related tasks like arrhythmia analysis, ST–values calculation, heart rate calculation, impedance and respiration rate calculation, energy expenditure calculation, EEG spectrum analysis and evoked potential response averaging. All the module communication is also handled in the main software. There are various optional types of keyboards, some are like standard keyboards and another is a hand-held Remote controller (REMCO) which is still directly connected to the S/5™ Compact Critical Care Monitor via a long cord but provides more flexibility in controlling the monitor while the doctor or nurse is handling other patient care needs. Using the recordkeeper software, patient related care events are documented using the keyboard. To facilitate quick access to menus, a bar code reader is also available.

The S/5™ Compact Critical Care Monitor can be in a stand-alone or networked configuration. If networked, measurements are sent to the network for central station or monitor-to-monitor viewing. Trends as well as the patient care documentation can be sent via a network to a central computer for archiving.

INTENDED USE as required by 807.92(a)(5)

The S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 is intended for multiparameter patient monitoring.

The S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion and neurophysiological status of all hospital patients.

The S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software is indicated for use by qualified medical personnel only.

SUMMARY OF TECHNOLOGICAL CHARACTERITICS OF DEVICE COMPARED TO THE PREDICATE DEVICE as required by 807.92(a)(6)

The Datex-Ohmeda S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software is substantially equivalent when compared to CS/3™ Monitors (K974792), and for bedside arrhythmia analysis and drug calculator as compared to CS/3 Critical Care Monitor with S-ICU99(A) software (K000168).

The S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software is a modular multi-parameter patient monitor. It is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, gastrointestinal/regional perfusion and neurophysiological status of all hospital patients. The S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software is indicated for use by qualified medical personnel only.

There are two software options available for the S/5™ Compact Critical Care Monitor:

- S-00C03: S/5™ Critical Care software
- S-00C04: S/5™ Critical Care software with extended arrhythmia analysis

The notation S-00C03/4 is used to refer to both software options collectively.

The S/5™ Compact Critical Care Monitor with S-00C03/4 software is a new revision of the predicate devices CS/3 Monitors (K974792). The two software options available for the S/5™ Compact Critical Care Monitor: S-00C03 and S-00C04 are identical except for the extended arrhythmia analysis capability. These enhancements do not affect efficacy or safety of the monitor.

The general construction and indications for use are similar to the predicate CS/3™ Monitors (K974792). With the S/5™ Compact Critical Care Monitor with S-00C03/4 software, there is a possibility to monitor some new measurement parameters. These new parameters, however, are located in separate measurement modules that are subject to separate 510(k) pre-market notification. Thus, they are not the subject of this submission. The S/5™ Compact Critical Care Monitor with S-00C03/4 software is thus substantially equivalent to the CS/3™ Monitors (K974792).

When the extended bedside arrhythmia analysis capability and drug calculator is compared, the S/5™ Compact Critical Care Monitor with S-00C04 software is identical to CS/3™ Critical Care Monitor with S-ICU99(A) software (K000168). Both monitors also use the same parameter modules.

As demonstrated in the detailed analysis in this document, the Datex-Ohmeda S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software is as safe and as effective as the predicates:

- CS/3™ Monitors (K974792)
- CS/3™ Critical Care Monitor with S-ICU99(A) software (K000168).

The detailed comparison in the 510(k) shows that there are no new questions of safety and effectiveness for the S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software. Based on the above analysis and other documentation included in this 510(k) notification and attachments, it is evident that the main features and indications for use of the S/5 Compact Critical Care Monitor with S-00C03 or S-00C04 software is substantially equivalent to the combination of the CS/3 Monitors (K974792) and CS/3 Critical Care Monitor with S-ICU99(A) software (K000168).

SUMMARY OF NONCLINICAL TESTING FOR THE DEVICE and CONCLUSIONS as required by 807.92(b)(1)(3)

The S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software is in compliance with safety standards and is therefore safe and effective for the intended use. The device has been thoroughly tested including electrical safety, electromagnetic compatibility, mechanical and environmental tolerance, software validation and verification of specifications. Verification of compliance to the following mandatory and voluntary standards have been made:

- IEC 60601-1:1988+ Amdt.:1:1991 + Amdt. 2:1995
- EN 60601-1: 1990 + A1:1993+A2:1995+A13:1996
- CAN/CSA-C22.2 No.601.1-M90 +S1:1994+Amdt. 2:1998
- IEC60529 (1989)/EN 60529 (1991)
- IEC 60601-2-27:1994/EN 60601-2-27:1994
- IEC 60601-2-30:1995/EN 60601-2-30:1995
- IEC 60601-2-34:1994/EN 60601-2-34:1994
- IEC 60601-2-40:1998/EN 60601-2-40:1998
- IEC 60601-1-2(1993)/EN 60601-1-2:(1993)
- IEC 60601-1-4: 1996/EN 60601-1-4
- ISO 9918:1993/EN 864:1996
- ISO 9919:1992/EN865;1997
- ISO 7767:1997/EN12598:1999
- ISO 11196 (1995) + Corr. 1:1997/EN ISO11196(1997)
- IEC 60601-2-10:1987/HD 395.2.10:1989
- IEC 60601-2-26:1994/EN60601-2-26
- UL 2601-1:1997
- ANSI/AAMI ES-1 (1993)
- ANSI/AAMI EC57:1998
- FDA 21 CFR 898.12

Conclusion:
The summary above shows that there are no new questions of safety and effectiveness for the S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software as compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 2 2000

Joel C. Kent
Manager, Quality and Regulatory Affairs
Datex Ohmeda, Inc.
3 Highwood Drive
Tewksbury, MA 01876

Re: K002158
Trade Name: S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software
Regulatory Class: III (three)
Product Code: MHX
Dated: July 14, 2000
Received: July 17, 2000

Dear Mr. Kent:

This letter corrects our substantially equivalent letter of September 6, 2000, regarding the version number for the software.

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your

device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

510(k) Number (if known): K002158

Device Name: Datex-Ohmeda S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software

The S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software is indicated for monitoring of hemodynamic (including arrhythmia and ST-segment analysis), respiratory, ventilatory, – gastrointestinal/regional perfusion and neurophysiological status of all hospital patients.

The S/5™ Compact Critical Care Monitor with S-00C03 or S-00C04 software is indicated for use by qualified medical personnel only.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 CFR 801.109) OR Over-The-Counter Use ____

(Optional Format 1-2-96)

Brian E. Harrington

Division of Cardiovascular & Respiratory Devices

510(k) Number K002158